UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI

UNITED STATES OF AMERICA,	)	
	)	
	)	
vs.	)	**Case No. 4:19CR591 ERW/NAB**
	)	
	)	
ABDUL NAUSHAD and	)	
WAJIHA NAUSHAD	)	
	)	
Defendants.	)	

JOINT MOTION TO DISMISS
SECOND SUPERSEDING INDICTMENT

Comes now the Defendants, Abdul Naushad ("Dr. Naushad") and Wajiha Naushad ("Mrs. Naushad"), by and through counsel, J. Alex Little and Khalid Kahloon, and respectfully move, pursuant to the Fifth and Sixth Amendments to the U.S. Constitution and Rules 7(c), 12(b)(2), 12(b)(3)(B), and 47 of the Federal Rules of Criminal Procedure, to dismiss the second superseding indictment.

As the basis for their motion, Defendants rely on the facts, arguments, cases, and authorities cited in this motion, as well as any facts, arguments, and authorities raised at a hearing on the issue, which they specifically request. Their motion should be granted for the reasons below:

INTRODUCTION

This case is a criminal prosecution seeking to enforce FDA regulations involving medical device labels. This sort of violation is known as "misbranding." The government has alleged that the labels of the medical devices that Dr. Naushad administered to his patients (known as Orthovisc) did not provide adequate directions

for use or adequate warnings. Due to these alleged deficiencies, the government has charged the Defendants with receiving and delivering misbranded devices for pay and fraud.

Although the government's misbranding case is without merit, its prosecution is even more troublesome, as it charged the Defendants with additional regulatory violations related to adulteration based on the same facts it used to support the misbranding charges. *See* Counts 8-13. This was error for two reasons: (i) the statute the government relies on to support the adulteration counts does not apply to these facts, and (ii) the indictment itself fails to allege a critical element of the crime of adulteration. With that element missing, the government has attempted to create a "new" crime that has no statutory basis.

But the second superseding indictment's faults do not stop there. Even if the Court were to accept the government's newfangled (and counter-textual) theory of "adulteration," there is another Constitutional problem: If improper labeling renders a device "adulterated," rather than simply "misbranded," every instance of criminal misbranding will necessarily meet the elements of criminal adulteration. Prosecution for both crimes therefore violates the Double Jeopardy Clause of the Fifth Amendment. As a result, the Court must require the government to elect whether it will proceed to trial on the adulteration counts or the misbranding counts. It cannot proceed to trial against the Defendants (and seek to punish them) on both charges based on the same conduct.

In addition to the arguments presented in this motion, the Defendants also hereby incorporate the arguments relating to the adulteration and fraud counts in their motion to dismiss the original indictment (Dkt. 45) and their Objections to the Report and Recommendations. (Dkt. 86). The Defendants understand those issues already have been decided by the Court but re-raise them here to avoid any possibility that they may be deemed waived in the future.

BACKGROUND

The Food, Drug, and Cosmetic Act ("FDCA") regulates—among other things—the manufacture and distribution of medical devices. Orthovisc is a medical device, but a simple one at that. It is nothing more than an inert chemical substance that lubricates certain human joints to reduce pain and increase mobility. Under the relevant regulations, Orthovisc is classified as a class III medical device.

Because of the risks associated with class III devices, manufacturers of such devices must submit premarket approval ("PMA") applications to the FDA and obtain premarket clearance before offering the devices for sale. *Battaglia v. United States*, 552 U.S. 312, 315-317 (2008). The application process is "rigorous" and typically includes, among other things, "full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operations"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of, such device"; samples of

device components required by the FDA; and a specimen of the proposed labeling." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318 (2008).

The FDA then spends, on average, more than 1000 hours reviewing the application. *Id*. After completing its review, the FDA can grant or deny premarket approval. *Id*. at 319 (citing § 360e(d)). It also can condition approval on adherence to performance standards. *Id*. (citing 21 CFR § 861.1(b)(3)). If the FDA cannot approve a new device, it may send an "approvable letter" indicating that the application could be approved if the applicant submits certain information or agrees to certain conditions or restrictions. *Id*. (citing 21 CFR § 814.44(e)). Alternatively, the FDA may send a "not approvable" letter that lists the grounds that justify denial along with, where practical, measures that the applicant could undertake to make the device approvable. *Id*. (citing § 814.44(f)). Between the time a manufacturer receives one of these letters and the time it submits the requested material and/or takes appropriate action to become approved, the PMA application is "not in effect."

Once approved, the device manufacturer must abide by many post-approval regulations. *See id*. If a manufacturer does not abide by these restrictions, then the FDA can take action by suspending or withdrawing approval of the application. *Id*.; 21 C.F.R. § 814.47. If a device's PMA application is "suspended or otherwise not in effect," it is considered "adulterated" pursuant to 21 U.S.C. § 351(f)(1)(B).

Some of the post-approval regulations involve labeling. For example, if a device manufacturer or distributor alters a label in one of the many ways described in 21 U.S.C. § 352, the device is considered "misbranded." Receiving and delivering a

misbranded device for pay violates 21 U.S.C. § 331(c). In addition, the FDA can take action on the manufacturer's PMA application, including by suspending or withdrawing it, based on misbranding violations (typically by the manufacturer). If it does, the devices are considered "adulterated" under 21 U.S.C. § 351(f)(1)(B). Once the devices are classified as "adulterated" because the PMA application is "not in effect," receiving and delivering the devices for pay will violate § 331(c) because the devices, in addition to being misbranded, are also adulterated.

SUMMARY OF ARGUMENT

In Counts 8-13, the indictment alleges that the Orthovisc at issue was "adulterated" pursuant to 21 U.S.C. § 351(f)(1)(B). But this is not true as a matter of law—as the statutory language demonstrates and the indictment itself acknowledges.

To validly charge a regulatory crime related to "adulteration" under section 351(f)(1)(B), the Orthovisc at issue must have a PMA application that is either (1) suspended or (2) otherwise *not* in effect. But the indictment fails to allege either theory—probably because Orthovisc's PMA *is* "in effect." *See* Indictment, at ¶ 23. To square this circle, then, the indictment relies on a third (invalid) theory of adulteration.

In the government's view, because the labeling of the Orthovisc at issue does not match the approved labeling contained in the PMA, it is a completely different device—a "foreign version." Thus, the indictment alleges, *this* Orthovisc should be considered "adulterated" under § 351(f)(1)(B). There is no legal support for the

government's theory, however, and it does not make sense in the statutory scheme. But, even more clearly, it does not fit the elements of the statute it relies upon. The counts alleging "adulteration" should be dismissed, because the crime alleged simply does not exist.

In the alternative, if the Court accepts the government's newfangled theory of what makes a device "adulterated," it should require the government to elect between the counts alleging "misbranding" and those alleging "adulteration" because, if the government's adulteration theory is accepted, when a device is "misbranded," it is necessarily also "adulterated." Punishing a defendant twice for the same conduct violates the Fifth Amendment's Double Jeopardy Clause and renders the counts multiplicitous.

ARGUMENT

I. As a matter of law, the Defendants did not violate 21 U.S.C. § 351(f)(1)(B), as alleged in Counts 8-13, because what the government has alleged is not a crime.

The indictment says that the Orthovisc at issue was "adulterated" because it violated 21 U.S.C. § 351(f)(1)(B), *see* Indictment, at ¶ 50, which says that the following devices are adulterated:

> (1) If it is a class III device—
>
> > (B)
> > (i) which was classified under section 360c(f) of this title, which under section 360e(a) of this title is required to have in effect an approved application for premarket approval, and which is not exempt from section 360e of this title under section 360j(g) of this title, and
> >
> > (ii) **which has an application** which has been suspended or is otherwise not in effect;

(emphasis added).

In other words, a class III device is adulterated if it has a PMA application that has been suspended or is "not in effect" for some other reason. And there are a few possible reasons that could be. For example, the FDA has the power to temporarily suspend a PMA under 21 C.F.R. § 814.47. In addition to being suspended, an approved application may not be "in effect" because it has been withdrawn under 21 C.F.R. § 814.46. Another reason that a PMA may not be "in effect" is that the FDA could be awaiting amendments to the PMA under 21 C.F.R. § 814.44. In any case, to charge a violation of § 351(f)(1)(B), the government must allege that an application is either (i) suspended or (i) not in effect for a different reason.

Here, the indictment fails to allege that Orthovisc's PMA application has been suspended or is otherwise not in effect. To the contrary, the government admits that Orthovisc has a PMA in effect. *See* Indictment, at ¶ 23. This fact is fatal to the § 351(f)(1)(B) adulteration charges. Because there is an approved PMA in effect for Orthovisc, the device cannot be adulterated *as a matter of law*, and the indictment must be dismissed.

The government's arguments to the contrary are meritless. In an attempt to get around the plain language of the statute, the government invents its own language—which has no basis in the text of the criminal statute or the statutory scheme of the FDCA as a whole. Specifically, the government alleges that, because the labeling of the Orthovisc at issue here does not match the approved labeling in the PMA, *this* Orthovisc is not really Orthovisc at all—it is a different device. The

government calls it a "foreign version," a term of its own making that has no place in the statute.

When the government begins to allege that something is illegal by making up words, and those words are not in the statute, the Court should take notice. The government cannot force a defendant to trial by saying up is down and down is up, and claiming this dispute is a factual one.

The weakness of the government's argument is apparent not only from its lack of a statutory basis, but also from its lack of logic. Under the government's theory, an artificial knee (which is a medical device) somehow loses its status as an approved medical device (and thus becomes "adulterated") if it is shipped in a box that has an illegible label due to poor printing by the box manufacturer. To be sure, the smudged ink may render the artificial knee "misbranded" under the relevant FDA regulations, but it does not call into question (or instantly overturn) the months- and years-long PMA approval process such that the device itself is now without a valid PMA "in effect." The FDA must take specific action, outlined in detailed regulations, to suspend or withdraw an approved PMA. These regulations and the words of the criminal statute have meaning, and they must be given effect.

But that's not the only reason to dismiss the adulteration charges. Even if the Orthovisc at issue in this case were somehow a "new device" that never had been approved before, and did not have an approved PMA "in effect," the statute cited in the indictment—§ 351(f)(1)(B)—would not make the Orthovisc "adulterated." This is because, in order to violate 21 U.S.C. § 351(f)(1)(B), there must be an approved

application to begin with. *See* § 351(f)(1)(B)(ii) (defining a device as "adulterated" when the device "*has an application* which has been suspended or is otherwise not in effect"). Nowhere does the indictment allege that this new, "foreign version" of Orthovisc "has an application" let alone that the application "has been suspended or is otherwise not in effect." Because the indictment fails to allege all of the elements of the crime, Counts 8-13 must be dismissed.

II. In the alternative, the Court should require the government to make an election between the counts charging adulteration (Counts 8-13) and misbranding (Counts 2-7) because they are multiplicitous.

A multiplicitous indictment is one that charges a single offense in multiple counts. *See, e.g., United States v. Worthon*, 315 F.3d 980, 983 (8th Cir. 2003). The danger of multiplicity is that it may lead to a defendant receiving multiple punishments for a single offense. *United States v. Roy*, 408 F.3d 484, 492 (8th Cir. 2005). In this manner, multiplicity violates the Fifth Amendment's Double Jeopardy Clause, which "protects against multiple punishments for the same offense." *United States v. Hinkeldey*, 626 F.3d 1010, 1013 (8th Cir. 2010) (citing *Brown v. Ohio*, 432 U.S. 161, 165 (1977) (internal quotation omitted)).

The test to determine whether a violation of two different statutory provisions constitutes the same offense is set forth in *Blockberger v. United States*, 284 U.S. 299, 304 (1932). The *Blockberger* test embodies the presumption that Congress "ordinarily does not intend to punish the same offense under two different statutes." *Whalen v. United States* 445 U.S. 684, 691-92 (1980). The analysis is straightforward: "Where the same act or transaction constitutes a violation of two distinct statutory provisions,

the test to be applied to determine whether there are two offenses or only one is whether each [statutory] provision requires proof of an additional fact which the other does not." *Blockberger*, 284 U.S. at 304; *see also Rutledge v. United States*, 517 U.S. 292, 297 (1996). Put another way, the *Blockberger* test asks whether each offense contains an element not contained in the other; if not, they are the "same offense" and punishment for both crimes violates double jeopardy.

Applying the *Blockberger* test here, the adulteration counts are the "same offense" as the misbranding counts. As a preliminary matter, the government brings both its adulteration counts (Counts 8-13) and its misbranding counts (Counts 2-7) pursuant to 21 U.S.C. § 331(c), which renders unlawful "[t]he receipt in interstate commerce of any . . . device. . . that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise." (emphasis added).

The only difference between the adulteration counts and the misbranding counts is that government must prove that the device is "adulterated" for the former and "misbranded" for the latter. Thus, to avoid multiplicity, "adulteration" and "misbranding" must mean different things. Properly understood, "adulteration" and "misbranding" *do* mean different things. But the government's (incorrect) theory of adulteration posits otherwise. Here's how:

If one accepts the government's (incorrect) claim that unapproved labeling renders a device adulterated, the logic is easy to follow:

1. Since misbranded labeling is not approved by the FDA, and
2. Labeling that is not approved by the FDA makes a device adulterated, then

3. All devices with misbranded labeling are also adulterated.

Applying these principles (with their flawed premises) to this case, the government has alleged that the Orthovisc at issue lacks adequate directions for use and adequate warnings under 21 U.S.C. §§ 352(f)(1) and (2). If the government proves those allegations, it also necessarily would have proven that the labeling was "not approved" and, thus, "adulterated." This means that the same facts would establish both the misbranding and adulteration offenses without the need to prove any additional or different elements between the two sets of charges. As a result, the separate charges are the "same offense," *see* 284 U.S. at 304, and attempting to punish the Defendants for both of them violates the Double Jeopardy Clause.

This multiplicity problem demonstrates again why the adulteration counts should be dismissed—no rational statutory scheme would operate this way. But, if the Court does not dismiss the adulteration counts for the reasons raised in this motion and in the original motion to dismiss, the Court should require the government to elect to proceed to trial on *either* the adulteration counts or the misbranding counts, but not both. If the Court does not, the Defendants will be severely prejudiced at trial.

Because multiplicitous indictments may suggest to the jury that the defendant committed more than one crime, the Court can force the government to elect the counts on which it chooses to proceed. *See United States v. Platter*, 514 F.3d 782, 786 (8th Cir. 2008); *United States v. Johnson*, No. 4:08CR107-DJS, 2008 WL 2079108 at *2 (E.D. Mo. May 15, 2008) ("[Requiring the government to elect] is most appropriate

when the mere making of the charges would prejudice the defendant with a jury." (citation omitted)).

The prejudice of allowing multiplicitous counts to go to trial is that the sheer number of counts "may falsely suggest to a jury that a defendant has committed not one but several crimes." *United States v. Johnson*, 130 F.3d 1420, 1426 (10th Cir. 1997) (citing *United States v. Duncan*, 850 F.2d 1107, 1108 n.4 (6th Cir. 1988)); *see also United States v. Marquardt,* 786 F.2d 771, 778 (7th Cir.1986) (multiple indictments create the impression of more criminal activity than in fact occurred)). "Once such a message is conveyed to the jury, the risk increases that the jury will be diverted from a careful analysis of the conduct at issue," and will reach a compromise verdict or assume the defendant is guilty on at least some of the charges. *Id*.

Here, given the complex nature of the regulatory violations alleged in the indictment, the danger of a compromised verdict is heightened. And, because the charges at issue involve two different sets of regulations, the jury is more likely to believe that the Defendants committed multiple crimes for each alleged violation of § 331(c), instead of just one crime.

Nor can a jury instruction cure this prejudice, as any instruction attempting to fix the multiplicity issue at trial is likely to (further) confuse the jury, especially given how complicated the instructions are already likely be due to the various complex regulations that the jury will have to try to understand and analyze.

For these reasons, the Defendants will be prejudiced by going to trial on these multiplicitous counts. Thus, if the Court does not dismiss the adulteration charges, it

should exercise its discretion and require the government to elect a single set of counts on which it will proceed.

CONCLUSION

WHEREFORE, for all the reasons detailed above, the Defendants respectfully request that the Court grant the joint motion to dismiss the second superseding indictment.

Respectfully submitted,

/s/ J. Alex Little
J. Alex Little (029858TN)
Zachary Lawson (036092TN)
Burr & Forman LLP
222 2nd Ave S, Suite 2000
Nashville, TN 37201
Telephone: 615-724-3203
alex.little@burr.com
Attorney for Defendant Abdul Naushad

/s/ Khalid Kahloon (w/permission)
Khalid Kahloon
Kahloon Law Office
600 West Main Street, Suite 500
Louisville, KY 40202
Telephone: 502-271-7200
kahloon@msn.com
Attorney for Defendant Wajiha Naushad

CERTIFICATE OF SERVICE

I hereby certify that on September 21, 2020, I electronically filed with the Clerk of the Court using the CM/ECF system upon:

Dorothy L. McMurty
U.S. Department of Justice
Office of U.S. Attorney
111 S. Tenth Street, 20th Floor
St. Louis, MO 63102
Email: dorothy.mcmurty@usdoj.gov

/s/ J. Alex Little